

Washington Law Review

Volume 72
Number 1 *Dedication to John Charles Huston*

1-1-1997

***In re Mahurkar*. The Federal Circuit's Misapplied Focus on Commercialization in "On Sale" Bar Analysis**

Hugh H. Matsubayashi

Follow this and additional works at: <https://digitalcommons.law.uw.edu/wlr>



Part of the [Intellectual Property Law Commons](#)

Recommended Citation

Hugh H. Matsubayashi, Notes and Comments, *In re Mahurkar: The Federal Circuit's Misapplied Focus on Commercialization in "On Sale" Bar Analysis*, 72 Wash. L. Rev. 267 (1997).

Available at: <https://digitalcommons.law.uw.edu/wlr/vol72/iss1/11>

This Notes and Comments is brought to you for free and open access by the Law Reviews and Journals at UW Law Digital Commons. It has been accepted for inclusion in Washington Law Review by an authorized editor of UW Law Digital Commons. For more information, please contact cnyberg@uw.edu.

IN RE MAHURKAR: THE FEDERAL CIRCUIT'S MISAPPLIED FOCUS ON COMMERCIALIZATION IN "ON SALE" BAR ANALYSIS

Hugh H. Matsubayashi

Abstract: In *In re Mahurkar Double Lumen Hemodialysis Catheter Patent Litigation*, the Federal Circuit held that a "sham" sale of an invention did not implicate the statutory "on sale" bar, which makes unpatentable any invention placed on sale more than one year prior to the filing of a patent application. This Note analyzes the *Mahurkar* decision's focus on the lack of commercialization of the invention in finding that a valid U.C.C. sale of an invention already reduced to practice does not implicate the "on sale" bar. It argues that under traditional "on sale" bar standards, a commercialization analysis is only necessary for the purposes of determining the degree of development of the invention and whether the sale was for experimentation purposes. It concludes by highlighting the inconsistency the Federal Circuit has created with this newly-developed emphasis on commercialization, necessitating a clarification of the policies and guidelines for proper application of the "on sale" bar.

A patent for an invention grants an inventor a federal statutory right to exclude others from making, using, and selling the invention throughout the United States and its territories.¹ In exchange for this exclusive right to exploit an invention, the inventor must disclose to the public the nature and content of invention.² To obtain a patent, the inventor also must comply with a number of conditions, including a prohibition against placing the invention on sale more than one year prior to applying for the patent.³

In *In re Mahurkar Double Lumen Hemodialysis Catheter Patent Litigation*,⁴ the Court of Appeals for the Federal Circuit affirmed a district court's determination that a "sham" sale of hemodialysis

1. 35 U.S.C. § 154 (1994). Section 154 provides in part:

Every patent shall contain . . . a grant to the patentee . . . of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States . . . or importing [the invention] into the United States . . .

[S]uch grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under section 120, 121, or 365(c) of this title, from the date on which the earliest such application was filed.

§ 154.

2. See 35 U.S.C. § 112 (1994) (requiring that inventor provide disclosure sufficient to enable person skilled in relevant art to make and use invention).

3. 35 U.S.C. § 102 (1994).

4. 71 F.3d 1573 (Fed. Cir. 1995).

catheters did not result in invalidation of the patent on those catheters.⁵ The Federal Circuit stressed that the lack of commercialization of the catheter was its central focus in determining whether the invention was "on sale" more than one year prior to the filing date of the patent application.⁶

Mahurkar raises several questions regarding the application of the "on sale" bar, such as what constitutes a "sale" under 35 U.S.C. section 102(b) and the extent to which commercialization is to be considered in the analysis. Although the fact pattern in *Mahurkar*, involving sham sales, is one that is not likely to arise again in the near future, the court's holding creates confusion for practitioners, inventors, and courts seeking to properly apply the "on sale" bar.

This Note argues that the Federal Circuit should develop clearer policies and guidelines for the application of the "on sale" bar of section 102(b). Part I examines the development of the "on sale" bar in patent law. Part II provides a brief overview of *Mahurkar*. Part III discusses flaws in the *Mahurkar* court's analysis and identifies the way in which the Federal Circuit has lost track of its original purpose for discussing commercialization in the context of an "on sale" bar analysis. This Note concludes by highlighting the irreconcilable inconsistency the Federal Circuit has created by applying a different "on sale" bar standard while articulating it as the same test traditionally used under section 102(b). The development of clearer guidelines by the Federal Circuit is imperative.

I. PATENT LAW AND THE "ON SALE" BAR

A. *Theories of Patent Law*

Patent law protects new, unobvious, and useful inventions by conferring to the patent owner the right to exclude others from making, using, or selling the claimed invention in the United States for a term of twenty years from the date of the patent application.⁷ Congress's power to establish a national patent system arises from the U.S. Constitution, which provides that Congress shall have the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to

5. *Id.* at 1574.

6. *Id.* at 1577.

7. 35 U.S.C. § 154; see *supra* note 1; see also Donald S. Chisum & Michael A. Jacobs, *Understanding Intellectual Property Law* § 2A, at 2-8 to 2-9 (1995).

Authors and Inventors the exclusive Right to their respective Writings and Discoveries."⁸

Two competing theories have been proposed by commentators to support the existence of the patent system: the "bargain" theory and the "natural rights" theory.⁹ The bargain theory is premised on the notion that the granting of a patent rewards an inventor and encourages the inventor to disclose the science behind the invention to the public.¹⁰ Such disclosure benefits society by promoting the progress of science.¹¹ Natural rights theorists stress the government's duty to compensate inventors for disclosing their inventions because otherwise inventors have no incentive for disclosure.¹² The policies underlying patent law have been shaped by the fundamental tension caused by these competing theories.

B. Statutory Bars to Patentability

An inventor who has developed an otherwise patentable invention may lose the right to a patent if the application falls under one of the statutory bar provisions.¹³ The general purpose of these statutory bars is

8. U.S. Const. art. I, § 8, cl. 8.

9. Stephen R. Schaefer, *Envirotech Corp. v. Westech Engineering, Inc.: The On-Sale Bar to Patentability and Executory Sales Offers*, 75 Minn. L. Rev. 1505, 1510 (1991).

10. *Id.*

11. Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. Chi. L. Rev. 1017, 1024 (1989) (describing two mechanisms by which scientific progress is promoted by patent system as follows: "first, the prospect of obtaining a patent monopoly provides an incentive to invest in research to make new inventions; and second, the patent system promotes disclosure of new inventions and thereby enlarges the public storehouse of knowledge").

12. Schaefer, *supra* note 9, at 1510.

13. See 35 U.S.C. § 102 (1994). Section 102 lists seven conditions of patentability, which are described, in part, as follows:

A person shall be entitled to a patent unless—

(a) the invention was known or used by others in this country . . . before the invention thereof by the applicant for the patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent . . . , or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented . . . by the applicant . . . in a foreign country prior to the date of the application for patent in this country on an application . . . filed more than twelve months before the filing of the application in the United States, or

to require inventors to assert their right to a patent through the filing and prosecution of a patent application.¹⁴

The "on sale" bar originated in 1790, when Congress enacted the first U.S. Patent Statute that authorized the grant of a patent to anyone who invented something "not before known or used."¹⁵ Congress enacted a statutory bar provision in 1839 that prevented inventors from obtaining a patent where an application for patent was submitted over two years after placing the invention "on sale" or in "public use."¹⁶ Congress reduced the grace period from two years to one year in 1936,¹⁷ and the one year "on sale" provision remained virtually unchanged and was recodified as section 102(b) in 1952.¹⁸ The present manifestation of the "on sale" bar is

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent . . . , or

(f) he did not himself invent the subject matter sought to be patented, or

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it.

§ 102.

14. Donald S. Chisum, *Patents* § 6.01, at 6-3 (1996); see also *Minnesota Mining & Mfg. Co. v. Kent Indus., Inc.*, 409 F.2d 99, 100 (6th Cir. 1969) (quoting *Ushakoff v. United States*, 327 F.2d 669, 672 (Ct. Cl. 1964), and stating that "purpose of the 1-year statutory bar is to prevent an inventor from obtaining profits on his invention for a number of years and then at a later date obtaining a patent").

15. William C. Rooklidge & W. Gerard von Hoffmann, III, *Reduction to Practice, Experimental Use, and the "On Sale" and "Public Use" Bars to Patentability*, 63 St. John's L. Rev. 1, 5 (1988).

16. *Id.* at 5. The Patent Act of 1839 provided in part:

[N]o patent shall be held to be invalid, by reason of such purchase, sale, or use prior to the application for a patent as aforesaid, except on proof of abandonment of such invention to the public; or that such purchase, sale, or prior use has been for more than two years prior to such application for a patent.

Patent Act of 1839, ch. 88, § 7, 5 Stat. 353, 354 (1839), reprinted in Ernest B. Lipscomb III, 9 *Lipscomb's Walker on Patents* 54 app. (3d ed. 1990) [hereinafter *Walker on Patents*].

17. Chisum, *supra* note 14, at app. 19-55. Section 4887 of the Revised Statutes was amended to read in part:

[N]o patent shall be granted on any application for patent for an invention or discovery or a design which had been patented or described in a printed publication in this or any foreign country more than one year before the date of the actual filing of the application in this country, or which had been in public use or on sale in this country for more than one year prior to such filing.

Id. at app. 19-54 to 19-55.

18. Rooklidge & von Hoffmann, *supra* note 15, at 6. Section 102(b) of the Patent Act of 1952 provided in part:

A person shall be entitled to a patent unless . . . the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

described in section 102(b), which states that an inventor will not be entitled to a patent if the invention was on sale more than one year prior to the date of the patent application.¹⁹ The date one year prior to application is known as the critical date.²⁰

To invalidate a patent for an “on sale” bar violation, the party asserting the bar must demonstrate that “there was a definite sale or offer to sell more than one year before the application for the subject patent.”²¹ That party must also show that “the subject matter of the sale or offer to sell fully anticipated the claimed invention or would have rendered the claimed invention obvious by its addition to the prior art.”²² The ultimate determination of whether a product was placed on sale for the purposes of section 102(b) is a question of law, based on underlying facts.²³ The

35 U.S.C. § 102(b) (1952); see Chisum, *supra* note 14, at app.19-23 (noting that Reviser’s Notes on Patent Act of 1952 comment that no change was made in statutory bar paragraphs “other than that due to division into lettered paragraphs”).

19. The statute provides:

A person shall be entitled to a patent unless . . . the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States

35 U.S.C. § 102(b).

20. *In re Yarn Processing Patent Validity Litig.*, 498 F.2d 271, 277 (5th Cir. 1974); Chisum & Jacobs, *supra* note 7, § 2C[5][b], at 2-89 (“The period from the critical date to the filing date is, in a sense, a grace period. An inventor has up to one year to file a patent application after a public disclosure or commercial use of the invention.”).

21. *Ferag AG v. Quipp Inc.*, 45 F.3d 1562, 1566 (Fed. Cir.) (quoting *UMC Elec. Co. v. United States*, 816 F.2d 647, 656 (Fed. Cir. 1987)), *cert. denied*, 116 S. Ct. 71 (1995).

22. *Id.* Prior art is defined as any relevant knowledge, acts, descriptions, and patents that pertain to, but predate, the invention in question. *Mooney v. Brunswick Corp.*, 663 F.2d 724, 732 (7th Cir. 1981); *Infodek, Inc. v. Meredith-Webb Printing Co.*, 830 F. Supp. 614, 622 (N.D. Ga. 1993). The scope of the prior art is defined as that “reasonably pertinent to the particular problem with which the inventor was involved.” *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1535 (Fed. Cir. 1983) (quoting *In re Wood*, 599 F.2d 1032, 1036 (C.C.P.A. 1979)).

Obviousness is a term of art in patent law, codified in 35 U.S.C. § 103. Section 103 reads in part:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S.C. § 103. Anticipation is also a term of art and it refers to the disclosure in the prior art of an invention substantially identical with the claimed invention for which a patent is sought. 1 *Walker on Patents*, *supra* note 16, § 4:4, at 269.

23. *Ferag*, 45 F.3d at 1566 (citing *KeyStone Retaining Wall Sys. Inc. v. Westrock, Inc.*, 997 F.2d 1444, 1451 (Fed. Cir. 1993)).

Federal Circuit has noted that the area of law dealing with section 102(b) is unsuited to mechanical rules, due to the factual nature of the inquiry.²⁴

The Federal Circuit has stated that the determination of whether the "on sale" bar has been violated depends on the totality of the circumstances, considered in view of the policies underlying section 102(b).²⁵ These policies include the following: (1) "discouraging removal of inventions from the public domain that the public reasonably has come to believe are freely available;" (2) "favoring the prompt and widespread disclosure of inventions;" (3) "allowing inventors a reasonable amount of time following sales activity to determine the potential economic value of a patent;" and (4) "prohibiting [inventors] from commercially exploiting their inventions beyond the statutorily prescribed time."²⁶ The Court of Claims has stated that the one year grace period provided by Congress in section 102(b) represents a balance between these competing interests.²⁷

Although the Federal Circuit has identified these four underlying policies of the "on sale" bar, it is not necessary that all four policies be implicated in a particular application of the bar. For example, a placing of an invention "on sale" by an unrelated third party more than one year prior to the filing of an application for patent by another has the effect under section 102(b) of invalidating a patent directed to that invention.²⁸ Based on this third party "on sale" bar doctrine, the Court of Claims held that the policy against removing inventions from the public domain and the policy favoring early patent filing are of sufficient importance in and

24. *Western Marine Elec., Inc. v. Furuno Elec. Co.*, 764 F.2d 840, 844 (Fed. Cir. 1985) (holding that analysis under section 102(b) "encompasses an infinite variety of factual situations which, when viewed in terms of the policies underlying § 102(b), present an infinite variety of legal problems wholly unsuited to mechanically-applied, technical rules") (quoting *Philco Corp. v. Admiral Corp.*, 199 F. Supp. 797, 815 (D. Del. 1961)).

25. *Envirotech Corp. v. Westech Eng'g Inc.*, 904 F.2d 1571, 1574 (Fed. Cir. 1990).

26. *Id.* These policies were first identified in a student law review note, Patrick J. Barrett, Note, *New Guidelines for Applying the On Sale Bar to Patentability*, 24 Stan. L. Rev. 730 (1972), that delineates five policies underlying the "on sale" bar. William C. Rooklidge, *The On Sale and Public Use Bars to Patentability: The Policies Reexamined*, 1 Fed. Circuit B.J. 7, 7 (1991). The Court of Claims in *General Electric Co. v. United States*, 654 F.2d 55 (Ct. Cl. 1981), cited to that law review note as identifying the underlying policies of the "on sale" and "public use" bars, but modified the policy discussion into the four part analysis described above. *Id.* at 61; see also David W. Carstens & Craig Allen Nard, *Conception and the "On Sale" Bar*, 34 Wm. & Mary L. Rev. 393, 395 (1993) ("Because Congress has never defined what constitutes placing an invention on sale, the courts often have utilized these underlying policies to help frame the issues in cases dealing with the 'on sale' bar.").

27. *General Electric*, 654 F.2d at 61.

28. *Id.* at 61-62.

of themselves to invalidate a patent where the invention is sold by one other than the inventor.²⁹

C. Determining an "On Sale" Bar Violation

The finding of an "on sale" bar requires two elements: first, the invention must have been placed on sale;³⁰ and second, the invention must have been sufficiently completed in order for the sale to embody the subject matter of the invention.³¹

Under section 102(b), an actual sale is not required for a transaction to act as a statutory bar, and a single offer to sell is enough to bar patentability whether or not the offer was accepted.³² Where there is no sale, however, a definite offer to sell is an essential requirement of the "on sale" bar.³³ This definite offer requirement excludes merely indefinite or nebulous discussions about a possible sale, but can be met by a patentee's commercial activity that does not rise to the level of a formal offer under contract law principles.³⁴ A valid offer under notions of contract law, however, clearly meets this requirement.³⁵

29. *Id.* at 62.

30. *See, e.g.,* *Ferag AG v. Quipp Inc.*, 45 F.3d 1562, 1566 (Fed. Cir.), *cert. denied*, 116 S. Ct. 71 (1995).

31. *See, e.g.,* *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 623 (Fed. Cir.), *cert. dismissed*, 474 U.S. 976 (1985).

32. *Intel Corp. v. U.S. Int'l Trade Comm'n*, 946 F.2d 821, 830 (Fed. Cir. 1991) ("Even free distribution of a prototype may raise the on-sale bar if it is done to solicit a sale" but "[i]t is not a violation of the on-sale bar to make preparations for the sale of a claimed invention—an actual sale or offer to sell must be proved."); *A.B. Chance Co. v. RTE Corp.*, 854 F.2d 1307, 1311 (Fed. Cir. 1988); *In re Caveney*, 761 F.2d 671, 676 (Fed. Cir. 1985); *In re Theis*, 610 F.2d 786, 791–92 (C.C.P.A. 1979). The *Theis* court discussed the application of section 102(b) where no sale is completed:

For § 102(b) to apply, it is not necessary that a sale be consummated. It suffices that the claimed invention, reduced to practice, was placed on sale, i.e., offered to potential customers, prior to the critical date. . . . Even if no delivery is made prior to the critical date, the existence of a sales contract prior to that date has been held to constitute an "on sale" status for the invention if it has been reduced "to a reality."

Theis, 610 F.2d at 791–92 (citations omitted).

33. *RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1062 (Fed. Cir. 1989).

34. *Id.*

35. *Id.; see, e.g.,* *Buildex Inc. v. Kason Indus., Inc.*, 849 F.2d 1461 (Fed. Cir. 1988). In *Buildex*, the court stated:

It is not necessary that a sale be consummated for the bar to operate. Even if no delivery is made prior to the critical date, the existence of a sales contract or the signing of a purchase agreement prior to that date has been held to demonstrate an 'on sale' status for the invention.

Id. at 1464.

Nevertheless, although a definite offer to sell is an essential requirement of the "on sale" bar, it does not ipso facto satisfy the bar. Rather, the court must also consider the degree to which an invention is completed.³⁶ One early test, known as the "on hand" doctrine, required that a device be produced and on hand for delivery in order for an offer to sell that device to invoke the "on sale" bar.³⁷ After a number of cases created exceptions to the "on hand" doctrine,³⁸ the Second Circuit, in *Timely Products Corp. v. Arron*,³⁹ replaced the "on hand" rule with a three-part "reduction to practice" test.⁴⁰ Under the reduction to practice test, three prongs must be met before the "on sale" bar can be applied:

- (1) The complete invention claimed must have been embodied in or obvious in view of the thing offered for sale. . . .
- (2) The invention must have been tested sufficiently to verify that it is operable and commercially marketable. This is simply another way of expressing the principle that an invention cannot be offered

36. See *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 623 (Fed. Cir.), cert. dismissed, 474 U.S. 976 (1985).

37. *Barnag Barmer Maschinenfabrik AG v. Murata Mach., Ltd.*, 731 F.2d 831, 836 (Fed. Cir. 1984) ("For an invention to be on sale under the 'on hand' rule, 'a device incorporating the invention must have existed in its ordinary or contemplated usable form, and must have been on hand and ready for delivery more than one year prior to the patent application filing date.'") (quoting *Galland-Henning Mfg. Co. v. Dempster Bros.*, 315 F. Supp. 68, 80 (E.D. Tenn. 1970)).

38. Cf. *Amphenol Corp. v. General Time Corp.*, 397 F.2d 431, 436 (7th Cir. 1968); *J.L. Clark Mfg. Co. v. American Can Co.*, 256 F. Supp. 719, 730-35 (D.N.J. 1966); *Philco Corp. v. Admiral Corp.*, 199 F. Supp. 797, 817-18 (D. Del. 1961) (rejecting "on hand" doctrine altogether, reasoning that solicitation of orders for goods to be produced later was competitive use that should start running of one-year grace period under section 102(b)).

39. 523 F.2d 288 (2d Cir. 1975).

40. *Id.* Reduction to practice is a term of art and can occur in two forms. Constructive reduction to practice occurs when an inventor files a patent application fully disclosing the subject matter of the invention. 1 *Walker on Patents*, supra 16, § 4:40, at 416. This type of reduction to practice is irrelevant to the discussion at bar. Actual reduction to practice is achieved when an inventor builds an embodiment of the invention and tests it to determine that it will be operable in its intended functional setting. *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1445 (Fed. Cir. 1984). Actual reduction to practice has four requirements:

- (1) The invention must have been embodied in a physical or tangible form;
- (2) the physical embodiment relied on as a reduction must show every feature of the invention as defined in the claim or count in interference;
- (3) the reduction to practice must demonstrate the practicability or utility of the invention to those of ordinary skill in the art; and
- (4) the reduction to practice must have been appreciated by the inventor at the time it was made.

Rooklidge & von Hoffmann, supra note 15, at 3-4.

for sale until it is completed, which requires not merely its conception but its reduction to practice. . . .

(3) Finally, the sale must be primarily for profit rather than for experimental purposes.⁴¹

The *Timely Products* reduction to practice test was reconsidered in *Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd.*⁴² In *Barmag*, the Federal Circuit stated in dicta that the reduction to practice test, requiring an invention’s physical embodiment to begin the running of the section 102(b) time period, is not applicable in all cases.⁴³ The court indicated that one of the primary purposes of section 102(b) is to preclude an invention’s commercial exploitation that has the effect of expanding the period of exclusive rights granted by the statute, and the restrictive nature of the *Timely Products* test would defeat this policy in certain cases.⁴⁴ The court clarified that the second part of the *Timely Products* test⁴⁵ does not require commercial marketability in addition to requiring a reduction to practice.⁴⁶ Rather, an invention is deemed “operable and commercially marketable” once the invention is reduced to practice.⁴⁷

In *UMC Electronics Co. v. United States*,⁴⁸ the Federal Circuit explicitly held that reduction to practice is not an absolute requirement of the “on sale” bar.⁴⁹ The court noted that other regional circuits, in an

41. *Timely Products*, 523 F.2d at 302 (citations omitted).

42. 731 F.2d 831 (Fed. Cir. 1984).

43. *Id.* at 837. The *Barmag Barmer* decision states:

The *Timely Products* standard, while requiring less for “on sale” activity than the “on hand” test, is, nevertheless, restrictive in that an offer to sell, without the existence of a physical embodiment of what is offered, does not start the running of the time period. It is not difficult to conceive of a situation where, because commercial benefits outside the allowed time have been great, the technical requisite of *Timely Products* for a physical embodiment, particularly for a simple product, would defeat the statutory policy and we, therefore, do not adopt the *Timely Products* test as the answer in all cases.

Id. Nevertheless, the Federal Circuit agreed with the trial court that the more restrictive “reduction to practice” test had been met, and therefore did not have to address the specifics of a less stringent standard. *Id.*

44. *Id.* at 836–37.

45. The second requisite for a section 102(b) bar is that “[t]he invention must have been tested sufficiently to verify that it is operable and commercially marketable.” *Timely Products*, 523 F.2d at 302.

46. *Barmag Barmer*, 731 F.2d at 838.

47. *Id.*

48. 816 F.2d 647 (Fed. Cir. 1984).

49. *Id.* at 656.

attempt to shoehorn the reduction to practice concept into an "on sale" bar analysis, looked to see whether an invention was "sufficiently" reduced to practice for the purposes of the bar.⁵⁰ However, there are no degrees of reduction to practice; either it has or has not occurred.⁵¹ Therefore, by adopting a "sufficiently" reduced to practice requirement, the Federal Circuit in essence abandoned the reduction to practice test.⁵² Despite its rejection of the *Timely Products* reduction to practice test, the court declined to specify a standard for determining when something less than a complete embodiment of the invention will suffice under the "on sale" bar.⁵³ This holding fails to provide lower courts with sufficiently clear standards to apply, creating confusion for the courts and practitioners left to grapple with the issue.⁵⁴

D. The "Experimental Use" Negation of the "On Sale" Bar

An event that would otherwise constitute the placing of an invention "on sale" is not a statutory bar if the sale was incidental to experimentation.⁵⁵ This "experimental use" negation of the statutory bars is not stated in the patent statutes but is recognized by the courts on policy grounds.⁵⁶

50. *Id.* at 654-55.

51. *Id.* at 655 (quoting *Wolter v. Belicka*, 409 F.2d 255, 262 (C.C.P.A. 1969) (Rich, J., dissenting)).

52. *Id.* Although the court rejected a firm requirement that the invention be reduced to practice in order for it to be barred, it was careful to note the usefulness of a finding of a reduction to practice in an "on sale" bar analysis:

We do not reject "reduction to practice" as an important analytical tool in an on-sale analysis. A holding that there has or has not been a reduction to practice of the claimed invention before the critical date may well determine whether the claimed invention was in fact the subject of the sale or offer to sell or whether a sale was primarily for an experimental purpose. . . . Thus, we simply say here that the on-sale bar does not necessarily turn on whether there was or was not a reduction to practice of the claimed invention. All of the circumstances surrounding the sale or offer to sell, including the stage of development of the invention and the nature of the invention, must be considered and weighed against the policies underlying section 102(b).

Id. at 656.

53. *Id.*

54. See Michael R. Schacht, Note, *UMC Electronics v. United States: Should Reduction to Practice be a Requirement of the On Sale Bar?*, 12 U. Puget Sound L. Rev. 131, 152 (1988).

55. Chisum, *supra* note 14, § 6.02[7], at 6-99; see also Chisum & Jacobs, *supra* note 7, § 2C[5][b][v], at 2-93 ("A public use or sale is not a statutory bar if the inventor's primary purpose is to conduct experiments on the nature and utility of the invention.").

56. Chisum & Jacobs, *supra* note 7, § 2C[5][b], at 2-93; see also Chisum, *supra* note 14, § 6.02[7][b], at 6-101 (discussing two policies that experimental use doctrine seeks to balance as follows: "The first is to allow the inventor time to test and perfect his invention and to assess its

For a sale or use to be considered experimental for section 102(b) purposes, the inventor's activity must represent a bona fide effort to perfect the invention or to ascertain whether it will achieve its intended purpose.⁵⁷ Any commercial exploitation that does occur must be incidental to the primary purpose of experimentation to perfect the invention.⁵⁸ Nevertheless, the "on sale" bar may invalidate a patent for an invention offered for sale, even though the invention at the time of the offer is not ready for satisfactory commercial marketing.⁵⁹ The determination of whether an activity is experimental is based on the totality of the circumstances.⁶⁰

utility in operation. The second is to prevent inventors from extending the statutory period of monopoly by delaying filing for a patent while commercially exploiting the invention.").

Although commentators in the field continue to refer to experimental use as an "exception" to the statutory bars, *see, e.g.*, Chisum & Jacobs, *supra* note 7, § 2C[5][b], at 2-93, the Federal Circuit has specifically noted that experimental use negates a section 102(b) statutory bar:

[T]he Supreme Court [in *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126 (1877)] did not refer to "experimental use" as an "exception" to the bar otherwise created by a public use. More precisely, the Court reasoned that, if a use is experimental, even though not secret, "public use" is negated. This difference between "exception" and "negation" is not merely semantic.

....

Under this analysis, it is incorrect to impose on the patent owner . . . the burden of proving that a "public use" was "experimental." These are not two separable issues. It is incorrect to ask: "Was it public use?" and then, "Was it experimental?" Rather, the court is faced with a single issue: Was it public use under § 102(b)?

TP Labs., Inc. v. Professional Positioners, Inc., 724 F.2d 965, 971 (Fed. Cir. 1984). The Federal Circuit seemingly ignored the fact that, just one year prior to the decision in *TP Laboratories*, it had referred to experimental use as an exception. *In re Smith*, 714 F.2d 1127, 1135 (Fed. Cir. 1983) ("Where . . . the inventor made the allegedly public use, he has the burden of going forward with convincing evidence that the public use activities fall within the experimental use exception."); *see also In re Mann*, 861 F.2d 1581, 1582 (Fed. Cir. 1988).

57. *Pennwalt Corp. v. Akzona Inc.*, 740 F.2d 1573, 1581 (Fed. Cir. 1984).

58. *Id.* (citing *In re Smith*, 714 F.2d at 1135 ("The experimental use exception . . . does not include market testing where the inventor is attempting to gauge consumer demand for his claimed invention. The purpose of such activities is commercial exploitation and not experimentation.")); *see also Sinskey v. Pharmacia Ophthalmics, Inc.*, 982 F.2d 494, 498 (Fed. Cir. 1992) ("To establish that an otherwise public use or sale does not run afoul of section 102(b), it must be shown that the activity was 'substantially for purposes of experiment.'").

59. *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 836 (Fed. Cir. 1992); *Barmag Barmer Maschinenfabrik AG v. Murata Mach., Ltd.*, 731 F.2d 831, 838 (Fed. Cir. 1984).

60. *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 549 (Fed. Cir. 1990). Some of the circumstances relevant to experimental use have been described as follows:

[W]hether payment was accepted; whether public testing was necessary; whether the length of the test period was appropriate; whether progress records were kept; whether the inventor can introduce objective evidence of experimental intent; whether the alleged experimental activities

The 1877 U.S. Supreme Court decision, *City of Elizabeth v. American Nicholson Pavement Co.*,⁶¹ created the experimental use exception, but left confusion among the various circuit courts as to whether it was necessary that the experimentation be for the primary purpose of actually reducing the invention to practice, or whether experimentation could continue beyond reduction to practice.⁶² The Federal Circuit explicitly addressed this issue in *RCA Corp. v. Data General Corp.*,⁶³ which held that an actual reduction to practice bars a claim of experimental use.⁶⁴

II. OVERVIEW OF *MAHURKAR*

A. *Facts of the Case*

A double lumen catheter is a catheter composed of a pair of hollow tubes (lumens).⁶⁵ When inserted, one of the lumens removes blood from a blood vessel for processing in a dialysis machine, and the other returns the processed blood to the vessel near the point of removal.⁶⁶ In 1980, Sakharam Mahurkar first conceived the idea for a double lumen catheter, and that idea eventually gave rise to the patented invention entitled "Smooth Bore Double Lumen Catheter."⁶⁷ Mahurkar began work on his idea for a dual-lumen catheter in his kitchen, and finished his first assembly on January 1, 1981.⁶⁸ He obtained several patents for that catheter, but the patent at issue in this case is Number 4,583,968.⁶⁹ Unlike other similarly-used catheters that have two coaxial circular-

were aimed at claimed features of the device; and whether the inventor retained control over the activity.

William C. Rooklidge & Stephen C. Jensen, *Common Sense, Simplicity and Experimental Use Negation of the Public Use and On Sale Bars to Patentability*, 29 J. Marshall L. Rev. 1, 29-30 (1995) (footnotes omitted).

61. 97 U.S. 126 (1877).

62. Edward G. Poplawski & Paul D. Tripodi, II, *The Impact of Federal Circuit Precedent on the "On-Sale" and "Public-Use" Bars to Patentability*, 44 Am. U. L. Rev. 2351, 2385 (1995).

63. 887 F.2d 1056 (Fed. Cir. 1989).

64. *Id.* at 1061 ("[E]xperimental use, which means perfecting or completing an invention to the point of determining that it will work for its intended purpose, ends with an actual reduction to practice.").

65. *In re Mahurkar Double Lumen Hemodialysis Catheter Patent Litig.*, 71 F.3d 1573, 1574 (Fed. Cir. 1995).

66. *Id.*

67. *Id.*

68. *In re Mahurkar Double Lumen Hemodialysis Catheter Patent Litig.*, 831 F.Supp. 1354, 1356 (N.D. Ill. 1993).

69. *Mahurkar*, 71 F.3d at 1574.

shaped lumens, Mahurkar's catheter is made of two semicircular lumens that end in a conically tapered tip.⁷⁰

On February 1, 1982, prior to filing any patent applications for the double-lumen catheter, Mahurkar granted an exclusive license to Quinton Instruments Company (Quinton) to make, use, and sell these catheters.⁷¹ This license agreement, however, conditioned Quinton's exclusive status on Quinton making its first sale of Mahurkar's catheters by September 30, 1982, just eight months after the creation of the agreement.⁷²

As the September deadline approached, Quinton had not made a sale because it had been unable to manufacture the catheters according to Mahurkar's specifications.⁷³ Quinton was able, however, to make a few prototypes of Mahurkar's invention by hand that were used for testing. Despite Quinton's manufacturing problems, Wayne Quinton, the CEO of Quinton Instruments, decided to sell similar prototypes to retain the exclusive license. He contacted a longtime acquaintance, Christopher Blagg, the executive director of the Northwest Kidney Center, and asked Blagg to purchase some of the catheters as a personal favor.⁷⁴

Although the exact details of this transaction are unclear, several facts are undisputed. Wayne Quinton offered the catheters for sale and Blagg accepted the offer.⁷⁵ Northwest later received an invoice for twenty catheters at twenty dollars apiece, but subsequently failed to pay this invoice.⁷⁶ On August 31, 1982, Quinton shipped two catheters to Northwest, where they were placed in a closed cabinet and were never used.⁷⁷ Northwest did, however, pay for these two prototype catheters.⁷⁸

The trial court looked to several indices in making its determination that the delivered products were not intended to be used and were commercially unsellable. The catheters were manufactured by hand and contained several defects that left them, in the trial court's opinion,

70. *Id.*

71. *Id.*

72. *Id.*; see also *Mahurkar*, 831 F.Supp. at 1366.

73. *Mahurkar*, 831 F.Supp. at 1366.

74. *Id.*

75. *Id.*

76. *Id.*

77. *In re Mahurkar Double Lumen Hemodialysis Catheter Patent Litig.*, 71 F.3d 1573, 1574–75 (Fed. Cir. 1995).

78. *Id.* at 1574.

unsuitable as commercial products.⁷⁹ These devices, however, were of approximately the same construction as the prototypes that were used for testing in human subjects and were therefore usable as catheters.⁸⁰

The court also looked to the instructions that were included with the catheters delivered to Northwest.⁸¹ These instructions directed the user, prior to use, to sterilize the catheters for thirty minutes in an autoclave. An autoclave uses superheated water under high pressure, at 250 degrees Fahrenheit, to sterilize the catheters. If these directions were followed, the plastic catheters would have deformed or melted from the heat. Nevertheless, other methods of sterilization could have left the catheters unaltered and therefore usable.⁸²

Following the transaction with Northwest, Mahurkar protested to Quinton that the transaction had been a sham and that Mahurkar was therefore entitled to terminate Quinton's exclusive license.⁸³ The two parties eventually settled their differences, and Quinton maintained its exclusive licensee status. In April 1983, fourteen months after the creation of the licensing agreement and over seven months after the Northwest transaction, Quinton introduced Mahurkar's catheters into the market for widespread commercialization.⁸⁴

On October 3, 1983, more than one year after the transaction with Northwest but less than one year from the time the catheters were commercially marketed, Mahurkar filed a design patent⁸⁵ for his

79. *Mahurkar*, 831 F.Supp. at 1367. The trial judge stated:

I reject Mr. Green's testimony that these devices were merchantable in the trade in 1982; they were prototypes, not saleable devices, and were so crude that Quinton would not even have given them away, except for testing or a desire to retain its exclusive license. . . . The catheters were crudely formed, and the holes for the passage of blood were drilled by hand. . . . The edges of the drilled holes were rough, creating a risk of hemolysis . . . and there were dead spots where blood would stagnate, creating a risk of clotting. They were not radiopaque. The tip was not stiff enough for normal insertion using the Seldinger technique. These flaws prevented commercial sale.

Id.

80. *Id.*

81. *Id.*

82. *Id.*

83. *In re Mahurkar Double Lumen Hemodialysis Catheter Patent Litig.*, 71 F.3d 1573, 1575 (Fed. Cir. 1995).

84. *Id.*

85. There are three types of patents: utility, design, and plant. Chisum & Jacobs, *supra* note 7, § 2C[1], at 2-19. Utility patents cover new and useful inventions, design patents cover new and ornamental designs of useful articles, and plant patents cover new and distinct plant varieties. *Id.*

invention of the smooth bore double lumen catheter.⁸⁶ Mahurkar later filed a continuing application⁸⁷ for a utility patent on this invention, and this patent eventually issued on April 22, 1986, with the benefit of the design application’s filing date: October 3, 1983.⁸⁸

Impra Incorporated is a competing manufacturer of a smooth bore dual-lumen catheter that the trial court determined to be essentially identical to the catheter described in Mahurkar’s patent.⁸⁹ Mahurkar and Quinton filed suit against Impra in July 1990 for infringement of Mahurkar’s catheter patent.⁹⁰ Impra responded with several arguments, including the contention that Mahurkar’s patent was invalid because it violated the “on sale” bar of section 102(b). Impra argued the transaction with Northwest constituted a “sale” for purposes of section 102(b), and that because this sale occurred more than one year prior to the patent application filing date, the patent was invalid.⁹¹

B. The Court’s Holding and Reasoning

The trial court disagreed with Impra and held that Quinton’s transaction with Northwest Kidney Center did not trigger the “on sale” statutory bar.⁹² The Federal Circuit affirmed the trial court’s decision, holding that whether a device has been placed on sale is not subject to a mechanical rule, but rather depends on the totality of the circumstances, considered in view of the policies underlying section 102(b).⁹³

The court narrowed its “totality of the circumstances” test by stressing that commercialization is the central focus for determining whether a patented invention has been placed on sale.⁹⁴ The court then concluded

86. *Mahurkar*, 71 F.3d at 1575.

87. A continuation allows an inventor to reapply for a different patent on an invention for which a patent application has already been filed. *See generally*, Chisum & Jacobs, *supra* note 7, § 2D[4][b], at 2-180. One of the benefits of the continuation is that the later application receives the same filing date as the prior application, which is used to determine the critical date for statutory bar purposes. *Id.*

88. *Mahurkar*, 71 F.3d at 1574.

89. *In re Mahurkar Double Lumen Hemodialysis Catheter Patent Litig.*, 831 F.Supp. 1354, 1357 (N.D. Ill. 1993), *aff’d*, 71 F.3d 1573 (Fed. Cir. 1995).

90. *Mahurkar*, 71 F.3d at 1575.

91. *Id.*

92. *Mahurkar*, 831 F. Supp. at 1370.

93. *Mahurkar*, 71 F.3d at 1577; *see also supra* note 26 and accompanying text.

94. *Mahurkar*, 71 F.3d at 1577 (“Foremost . . . is the policy of preventing inventors from exploiting the commercial value of their inventions while deferring the beginning of the statutory term.”) (quoting *Ferag AG v. Quipp Inc.*, 45 F.3d 1562, 1565 (Fed. Cir. 1995)).

that the sale by Quinton to Northwest was a sham that did not result in commercialization of the invention nor place it in the public domain, and therefore no section 102(b) sale occurred.⁹⁵ This determination was made despite the fact that the prototype catheters delivered to Northwest did constitute a reduction to practice that embodied the claimed invention.⁹⁶ Furthermore, the court did not reject the trial court's finding that the transaction constituted a bona fide Uniform Commercial Code "sale" for nonexperimental purposes.⁹⁷

The court examined the facts surrounding the transaction and then determined that no commercialization took place. The court emphasized that Quinton did not advertise the catheters, nor did it offer them to anyone but Blagg prior to the critical date.⁹⁸ Northwest purchased the catheters outside the usual channels, and had it followed the included instructions, the catheters would have been rendered unusable for their intended purpose.⁹⁹

The court also considered the intent of the parties. Quinton and Northwest intended the transaction to be a special deal to satisfy the requirements of the licensing agreement; they did not intend it to be an ordinary commercial sale.¹⁰⁰ Furthermore, Mahurkar did not believe that Quinton had a marketable product and protested that the sale was a sham that did not satisfy the requirements of the licensing agreement.¹⁰¹

To provide additional support for the court's assertion that the Northwest transaction was not a section 102(b) sale, the Federal Circuit concluded its decision by analyzing the policies behind section 102(b).¹⁰² The sale to Northwest did not place the invention in the public domain, nor did it lead the public to believe that the device was freely available. Even in the unlikely chance that members of the public were aware of the transaction, the circumstances indicated that the transaction was a sham and not an ordinary commercial sale that would indicate that the invention was in the public domain. The court also stated that its decision was consistent with the policy of encouraging the prompt and widespread disclosure of inventions while allowing an inventor a reasonable amount

95. *Id.*

96. *Id.*

97. *Id.* at 1574, 1577.

98. *Id.* at 1577.

99. *Id.*

100. *Id.*

101. *Id.*

102. *See id.*

of time following sales activity to determine the potential value of a patent. Because the delivered catheters were unmarketable and unusable if the directions were followed, the court concluded that the transaction did not provide the inventor with information as to the value of the patent. This suggests that the transaction did not impermissibly extend the one-year period given to inventors for this type of evaluation.¹⁰³

III. FLAWS IN THE FEDERAL CIRCUIT’S ANALYSIS IN *MAHURKAR*

Although the factual elements of the *Mahurkar* case are fairly unique and unlikely to re-emerge in the future, the Federal Circuit’s decision amplifies the existing confusion in an already perplexing area of law. Notwithstanding the *Mahurkar* court’s assertion that it was following the policy-based “totality of the circumstances” analysis traditionally used in “on sale” bar cases, its analysis actually applied a misguided overemphasis on commercialization. This overemphasis was first applied by the Federal Circuit in *Ferag AG v. Quipp Inc.*,¹⁰⁴ but has its origins in the experimental use analysis that emerged from *Timely Products Corp. v. Arron*.¹⁰⁵

The *Mahurkar* court also erroneously focused on the quality of the products delivered to Northwest. As the catheters had already been reduced to practice and tested in human patients, proving their utility, flaws in the quality of the manufacturing of the catheters is irrelevant for section 102(b) purposes. The inappropriate examination of the quality of the invention sold, together with the emphasis on commercialization as the central policy focus, led the Federal Circuit to carve out an application of the “on sale” bar inconsistent with its prior case law.

A. *The Court’s Misapplied Focus on Commercialization*

The fundamental problem with the *Mahurkar* court’s analysis is that it emphasizes commercialization as the central focus in section 102(b) analysis.¹⁰⁶ *Mahurkar* grounds its focus in the Federal Circuit’s decision

103. *Id.*

104. 45 F.3d 1562 (Fed. Cir.), *cert. denied*, 116 S. Ct. 71 (1995).

105. 523 F.2d 288 (2d Cir. 1975).

106. *Mahurkar*, 71 F.3d at 1577. The court described its emphasis as follows:

Our court has stressed that commercialization is the central focus for determining whether the patented invention has been placed on sale. . . . Because we conclude that Quinton’s sale to Northwest was a sham that did not result in ‘commercialization’ of the invention or place it in

in *Ferag*, but a careful reading of that decision reveals that *Ferag*'s focus on commercialization is unfounded.

The *Ferag* decision was the first instance in which the Federal Circuit held that the foremost policy expressed by section 102(b) is to prevent inventors from exploiting the commercial value of their inventions while deferring the beginning of the statutory term.¹⁰⁷ The Federal Circuit in *Ferag* cited to its 1990 decision in *Envirotech Corp. v. Westech Engineering, Inc.*¹⁰⁸ to support this contention.¹⁰⁹ *Envirotech*, however, simply listed the various policies defining the "on sale" bar and provided no indication that any one policy weighed more heavily than the others.¹¹⁰ *Ferag*'s unsupported assertion regarding the primacy of the commercialization inquiry is made even more inscrutable by its juxtaposition with the assertion immediately preceding it, which acknowledges that no single factor controls the application of section 102(b).¹¹¹

In *U.S. Environmental Products, Inc. v. Westall*,¹¹² a case decided the same year as *Envirotech*, the Federal Circuit explained that the policy of preventing an inventor from commercially exploiting an invention beyond the statutory period is "[o]ne of the primary purposes of the on sale bar."¹¹³ However, the explanation given in *U.S. Environmental Products* only indicates that the commercial exploitation by the inventor is merely one of several policies underlying the "on sale" bar.¹¹⁴ It does

the public domain, no § 102(b) sale occurred even though the prototype was a reduction to practice of the invention.

Id. (citation omitted).

107. See *Ferag*, 45 F.3d at 1566 ("The underlying policies are what drives the section 102(b) analysis. . . . Foremost among these is the policy of preventing inventors from exploiting the commercial value of their inventions while deferring the beginning of the statutory term.") (citation omitted).

108. 904 F.2d 1571 (Fed. Cir. 1990).

109. *Ferag*, 45 F.3d at 1566.

110. See *Envirotech*, 904 F.2d at 1574. The primary point of *Envirotech* was that an inventor's attempted exploitation of an invention must be objectively manifested as a definite offer to sell the invention. *Id.* at 1575 ("While we agree that the policies underlying the 'on sale' bar concentrate on the inventor's attempt to exploit his invention rather than the potential purchaser's cognizance of it . . . the inventor's attempted exploitation must be objectively manifested as a definite offer to sell the invention.").

111. *Ferag*, 45 F.3d at 1566 ("While a wide variety of factors may influence the on sale determination, no single one controls the application of section 102(b), for the ultimate conclusion depends on the totality of the circumstances.") (citing *Envirotech*, 904 F.2d at 1574).

112. 911 F.2d 713 (Fed. Cir. 1990).

113. *Id.* at 715.

114. *Id.*

not advocate that any one policy carries a greater significance than the others.¹¹⁵

Envirotech and *U.S. Environmental* indicate that the *Ferag* court improperly focused its policy examination on commercialization, ignoring the great weight of case law requiring that courts consider each of the four "on sale" bar policies based on the totality of the circumstances. Although not all four policies need to be implicated in a particular application of the "on sale" bar,¹¹⁶ the placing of commercialization as the foremost policy concern creates an imbalance in the policy analysis. In *Ferag*, however, negative ramifications of this misapplied focus on commercialization were minimized because of the particular nature of that case. The key question in *Ferag* was whether the invention offered for sale by the patent owner, Ferag AG, embodied the invention claimed in the patent.¹¹⁷ It was undisputed that Ferag AG made a sale of a product, but the question was whether the "on sale" bar should be implicated, considering the buyer's lack of knowledge that the purchased product embodied the patented invention.¹¹⁸ The Federal Circuit held that the district court mistakenly relied on the seller's intent and the purchaser's understanding of the product.¹¹⁹ According to the

115. See *id.* ("One of the primary purposes of the on-sale bar is to prevent an inventor from commercially exploiting the exclusivity of an invention in excess of the statutorily authorized period."). To support this contention, the court cited to *General Electric Co. v. United States*, 654 F.2d 55, 61 (Ct. Cl. 1981). However, the *General Electric* decision was the first Federal Circuit decision to identify the four policies underlying the "on sale" bar, and it does not emphasize the importance of any one policy over the others. See *General Elec.*, 654 F.2d at 61. In fact, the court explained that "the policy against removing inventions from the public domain and the policy favoring early patent filing are of sufficient importance in and of themselves to invalidate a patent," even without implication of the other two "on sale" bar policies. *Id.* at 62.

116. See *supra* text accompanying note 28.

117. *Ferag AG v. Quipp Inc.*, 45 F.3d 1562, 1568 (Fed. Cir.), *cert. denied*, 116 S. Ct. 71 (1995). This was the same question addressed in *Envirotech*, but with some factual distinctions. *Id.*; see also *Envirotech Corp. v. Westech Eng'g Inc.*, 904 F.2d 1571, 1574-76 (Fed. Cir. 1990). In *Ferag*, Ferag AG, the owner of a patent for a conveyor apparatus, entered into a "Partnership Agreement" with the Bergen Evening Record (Bergen) that provided for the installation of two of Ferag AG's conveyor systems at Bergen's newspaper publishing facility. *Ferag*, 45 F.3d at 1564-65. The agreement listed rough price estimates and general performance criteria, but did not provide specific operational details about the systems. *Id.* at 1565. In *Envirotech*, the patent owner submitted a proposal for a digester cover on a city water treatment project, but, unlike the situation in *Ferag*, the patent owner's proposal specifically listed the use of an old design that did not cover the invention at issue. *Id.* at 1568; *Envirotech*, 904 F.2d at 1575. The Federal Circuit in *Envirotech* held that "the inventor's attempted exploitation must be objectively manifested as a definite sale or offer to sell the invention" and that the "subjective, uncommunicated, and ultimate intention of the offeror, however clear, is not alone sufficient." *Envirotech*, 904 F.2d at 1575.

118. *Ferag*, 45 F.3d at 1568.

119. *Id.*

Ferag court, the proper measure of the "on sale" bar is what was offered, not the patentee's intent.¹²⁰ Because *Ferag AG* intended to supply the patented invention to fill the purchase order, albeit without the knowledge of the purchaser, the sale constituted a commercialization of the invention prior to the critical date, thus implicating the "on sale" bar.¹²¹

In *Mahurkar*, there was a valid U.C.C. sale of a catheter that constituted a reduction to practice of the patented invention.¹²² Unlike *Ferag* and *Envirotech*, there was no question that the invention offered and sold in *Mahurkar* was the patented invention. The overemphasis on commercialization espoused in *Ferag* led the *Mahurkar* court to conduct its "on sale" bar analysis without fully addressing all of the policies underlying section 102(b).¹²³ Although the court mentioned the policy of encouraging prompt and widespread disclosure of inventions, it confused its analysis of that policy with its discussion of the policy of allowing an inventor time to determine the potential value of a patent.¹²⁴ After noting the policy of encouraging prompt disclosure, the court, without any further discussion, proceeded to apply the *Mahurkar* facts to the policy of allowing time to determine the patent's value.¹²⁵ The court did not explain how the policy of encouraging prompt and widespread disclosure

120. *Id.* The court noted that *Envirotech* recognized this and found no "on sale" bar violation because the proposal specified the prior art design, even though the patentee intended to provide the patented design for the project. *Id.*; see also *Envirotech*, 904 F.2d at 1575.

121. *Ferag*, 45 F.3d at 1568-69.

122. *In re Mahurkar Double Lumen Hemodialysis Catheter Patent Litig.*, 71 F.3d 1573, 1576 (Fed. Cir. 1995).

123. *Id.* at 1577.

124. The court first addressed the first and fourth policies of the "on sale" bar, described *supra* note 26, by stating, "Because we conclude that Quinton's sale to Northwest was a sham that did not result in 'commercialization' of the invention or place it in the public domain, no § 102(b) sale occurred even though the prototype was a reduction to practice of the invention." *Id.* The court later provided a brief discussion on the second and third policies, but failed to address satisfactorily the second policy of favoring the prompt and widespread disclosure of inventions:

That the Northwest transaction was not a § 102(b) sale is also consistent with encouraging the prompt and widespread disclosure of inventions and allowing an inventor a reasonable amount of time following sales activity to determine the potential value of a patent. The Northwest transaction was not "sales activity" that helped the inventor determine the value of a patent. Selling two unmarketable prototypes with instructions that made them unusable could not provide information as to the value of the patent. This suggests that the transaction did not impermissibly extend the one-year period allowed for inventors to evaluate the value of a patent before filing an application.

Id. at 1577-78.

125. See *supra* note 124.

of inventions would be consistent with a finding of no “on sale” bar violation in this case.¹²⁶

B. The Development of the Focus on Commercialization

Although the focus on commercialization as the central policy in “on sale” bar analysis in *Ferag* and *Mahurkar* was inappropriate, an analysis of the commercialization of an invention is appropriate in two circumstances. While the Federal Circuit has rejected the *Timely Products* reduction to practice test, this test clarifies the original purpose in using commercialization as a tool for determining the application of the “on sale” bar.¹²⁷ The proper use of commercialization is articulated in the second and third parts of the three-part reduction to practice test proposed in *Timely Products*.¹²⁸ The second prong requires that the invention be tested sufficiently to verify that it is operable and commercially marketable.¹²⁹ The third prong under *Timely Products* requires that a sale be “primarily for profit rather than for experimental purposes.”¹³⁰

Under the second prong, analysis of the commercial marketability of an invention is utilized for the purpose of determining the degree of completion of the invention.¹³¹ The “on sale” bar can therefore only be applied in cases where the invention is complete to a level at which it is operable and commercially marketable. As clarified in *Barmag Barmer*, an invention that is reduced to practice is considered to be operable and commercially marketable, and therefore any sales of that invention can implicate the “on sale” bar.¹³²

The third prong directs the court to determine whether the nature of the sale is primarily for profit rather than for experimental purposes.¹³³ The implication from the wording of this test is that an analysis of whether a sale is primarily for profit is only necessary insofar as it is required to demonstrate that the sale was not for experimental purposes.

126. See *supra* note 124.

127. See *supra* note 43 and accompanying text.

128. See *supra* text accompanying note 41.

129. *Timely Prods. Corp. v. Arron*, 523 F.2d 288, 302 (Fed. Cir. 1975).

130. *Id.*

131. *Id.*

132. *Barmag Barmer Maschinenfabrik AG v. Murata Mach., Ltd.*, 731 F.2d 831, 838 (Fed. Cir. 1984).

133. *Timely Products*, 523 F.2d at 302.

The language in several cases similarly reflects that the analysis of commercial exploitation is used only to determine whether a sale is primarily for a bona fide experimental purpose.¹³⁴ Moreover, such language provides no indication that commercial exploitation has any relevance beyond the experimentation analysis.¹³⁵

A proper application of a commercialization analysis under these two tests results in a finding that Mahurkar's catheter patent should be barred under section 102(b). In *Mahurkar*, neither of the above-described purposes for investigating the commercial aspects of a sale exists. The trial court determined that the catheters delivered to Northwest constituted a reduction to practice of the invention.¹³⁶ Thus, under *Barmag Barmer*, the invention was operable and commercially marketable, at least for section 102(b) purposes, despite its manufacturing flaws. Furthermore, the trial court found that the transaction between Quinton and Northwest was a sale under contract law for nonexperimental purposes.¹³⁷ Therefore, any further analysis into the commercial nature of the sale was rendered unnecessary.

C. *The Quality of the Delivered Catheter Was Irrelevant*

The *Mahurkar* court ignored the underpinnings of the commercialization inquiry largely because it became mesmerized by the low quality of the catheters delivered to Northwest. The actual quality of the product sold, however, is irrelevant if the invention already has been reduced to practice. The overemphasis placed on commercialization in *Ferag* provided the *Mahurkar* court with the tools to ignore the traditional balancing of policies used in "on sale" bar analyses prior to *Ferag*.

134. See, e.g., *Paragon Podiatry Lab., Inc. v. KLM Lab., Inc.*, 984 F.2d 1182, 1185 (Fed. Cir. 1993) ("[A] product embodying the patented invention, which is sold or offered for sale more than a year before the application's filing date, may escape the statutory bar where such sale was primarily for a bona fide experimental purpose to perfect the invention, rather than for commercial exploitation."); *Pennwalt Corp. v. Akzona Inc.*, 740 F.2d 1573, 1581 (Fed. Cir. 1984) ("Any experimentation over one year before an application's filing date must be for a bona fide experimental purpose rather than for commercial exploitation."); *In re Smith*, 714 F.2d 1127, 1135 (Fed. Cir. 1983) ("The experimental use exception, however, does not include market testing where the inventor is attempting to gauge customer demand for his claimed invention. The purpose of such activities is commercial exploitation and not experimentation.").

135. See *supra* note 134.

136. *In re Mahurkar Double Lumen Hemodialysis Catheter Patent Litig.*, 71 F.3d 1573, 1575-76 (Fed. Cir. 1995).

137. *Id.* at 1576.

In *UMC Electronics Co. v. United States*, the Federal Circuit explicitly rejected the reduction to practice requirement in section 102(b) analysis and held that the lack of a physical embodiment of the invention before the critical date did not prevent application of the “on sale” bar.¹³⁸ However, the Federal Circuit in *Mahurkar* focused much of its discussion on the quality of the delivered catheters. Despite the fact that the catheters constituted a reduction to practice of Mahurkar’s invention, the court focused much of its decision not to consider the sale as a section 102(b) bar based on the “usability” of the device.¹³⁹

The Federal Circuit emphasized that the delivered catheters were unusable if the directions were followed.¹⁴⁰ The trial court, however, found that the delivered product constituted a reduction to practice of the invention, and if another party were to make and sell identically unusable catheters, they would have been guilty of patent infringement.¹⁴¹ Once the trial court determined that the products constituted a reduction to practice of the invention, this should have ended any discussion of the quality of the products. That an offer to sell a device that has not yet

138. 816 F.2d 647, 656 (Fed. Cir. 1987).

139. See *Mahurkar*, 71 F.3d at 1577. The court stated:

Because we conclude that Quinton’s sale to Northwest was a sham that did not result in “commercialization” of the invention or place it in the public domain, no § 102(b) sale occurred even though the prototype was a reduction to practice

We believe that the relevant facts indicate that no commercialization took place here. . . . Mahurkar did not believe that Quinton had a marketable product that could be offered to customers. . . . Moreover, the catheters were unusable for their intended purpose by anyone who followed the instructions included with the catheters.

Id. (citation omitted).

140. See *id.* at 1575–77. The court made the following statements at various points throughout the decision:

The catheters had a number of serious defects, which would have increased the risk of injury to patients using the catheters for dialysis. The instructions accompanying both of the catheters directed the user to sterilize them in an autoclave at 250 degrees for 30 minutes before insertion in a patient. The district court found that treating the catheters according to these instructions would have melted the catheters, or at least deformed them, rendering them unusable.

. . . .

The Northwest transaction was not “sales activity” that helped the inventor determine the value of the patent. Selling two unmarketable prototypes with instructions that made them unusable could not provide information as to the value of the patent.

Id.

141. *In re Mahurkar Double Lumen Hemodialysis Catheter Patent Litig.*, 831 F. Supp. 1354, 1368 (N.D. Ill. 1993) (“I find that the devices furnished to the Northwest Kidney Center were ‘catheters’ and constituted a reduction to practice of the Mahurkar invention If IMPRA were to make and sell identical devices today, Mahurkar could contend, successfully, that they infringed claims 1 and 19 of the ‘968 patent.”), *aff’d*, 71 F.3d 1573 (Fed. Cir. 1995).

come into being can qualify as an "on sale" bar,¹⁴² while an actual contractually binding sale and transfer of a completed device does not, creates an illogical inconsistency in the Federal Circuit's developing "on sale" bar case law.

IV. CONCLUSION

The *Mahurkar* decision continues the Federal Circuit's misdirected focus on commercialization of an invention in "on sale" bar analyses. If the Federal Circuit intends to do away with the notion that an "on sale" bar analysis depends upon the totality of the circumstances in view of the four policies underlying section 102(b), it should do so explicitly. By placing commercialization as the foremost policy consideration, the court has disrupted the balance between the competing interests embodied in the four policies, leaving it unclear when and how each individual policy should be weighed.

Barring any attempt by the Federal Circuit to change the nature of the "on sale" bar analysis, a focus on commercialization is only necessary insofar as it is needed to determine the degree of completion of the patented invention at the time of sale, and whether the sale was for experimental purposes.

Although the decision in *Mahurkar* was articulated using the same "totality of the circumstances" policy-driven analysis traditionally used in "on sale" bar determinations, its focus on commercialization results in an irreconcilable inconsistency with prior applications of a commercialization analysis. The Federal Circuit's recent decisions in the "on sale" bar arena have left such confusion in its wake that the development of clearer guidelines is imperative.

142. See *UMC Elec. Co.*, 816 F.2d at 656.